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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,048	08/09/1999	NAPHTALI SAVION	0744/077	4662

27557 7590 12/02/2002

BLANK ROME COMISKY & MCCAULEY, LLP  
900 17TH STREET, N.W., SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/341,048

Applicant(s)

SAVION ET AL.

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 108-140 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 108-114, 116, 117, 129, 131-134 and 136-140 is/are rejected.
- 7) ☒ Claim(s) 115, 118-128, 130 and 135 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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Claims 108-140 are presented for examination.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 108-111, <sup>133,</sup>115, 116, 117, 133, 137 and 138 are rejected under 35 U.S.C. 102 (b) as being anticipated by the European Patent Application 0 312 814. The European Patent Application teaches the use of the claimed phospholipis in a pharmaceutical formulation for the treatment of dry eye syndrome. See page 2, summary of the invention and page 7 example 1.

Claims 135, 136, 139 and 140 are rejected under 35 U.S.C. 102 (b) as being anticipated by Levine et al.. Levine et al. Teach the use of HDL with phospholipid or glycerol and apolipoprotein A-1 in a pharmaceutical formulation. The presence of albumin is also taught by the above reference.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 112-114, ~~118-129~~, 131, 132, 134 and 140 are rejected under 35 U.S.C. 103 as being unpatentable over European Patent Application 0 312 814 in view of Pflugfelder et al.

(5,652,209), Levin (5,023,090).

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The European Patent Application teaches the use of the claimed phospholipids for the treatment of dry eye syndrome. See page 2, summary of the invention and page 7, example 1. The above reference differs from the claimed invention in the presence of a growth factor, laminin and fibronectin. Pflugfelder et al. teach the use of growth factors for the treatment of dry eye syndrome. See the abstract. Levin teaches the use of fibronectin and laminin for the treatment of dry eye syndrome. See page 16 paragraph 151. It would have been obvious to a person skilled in the art to incorporate the growth factor, fibronectin and laminin into the primary reference in view of the secondary references which teach the use of such compounds for the treatment of dry eye.

One skilled in the art would have been motivated to combine the teachings of the above references, since they all relate to the use of different claimed components individually being used for the treatment of dry eye. The combinations of ingredients being used for the same purpose is merely the additive effect of each individual component. See *In re kerkhoven*, 629 F.2d 848, 205 USPQ 1069 (CCPA 1980). It is generally considered prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

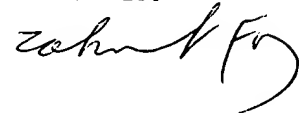
118-130

Claims 115, 118, 119, 120-128, 130 and 135 are rejected as being dependent on a rejected claim.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200

A handwritten signature in black ink, appearing to read 'Zohreh Fay', written over the printed name and title.

Z.F

November 21, 2002